CLAIMS

What is claimed is:

1. A composition comprising:
   a) a C12 to C24 branched or unbranched hydrocarbon;
   b) a mid-chain triglyceride;
   c) a C26 to C36 branched or unbranched hydrocarbon;
   d) a cholesteryl ester;
   e) an ester of a C10 to C24 fatty acid and a C10 to C20 alcohol;
   f) an ester of a C10 to C24 fatty acid and a C21 to C34 alcohol;
   g) glycerol; and
   h) a polar lipid.

2. The composition of Claim 1, which is substantially free of water.

3. The composition of Claim 1, which is substantially free of an artificial surfactant.

4. The composition of Claim 1, which is in a form chosen from an ointment, a paste, and a cream.

5. The composition of Claim 1, wherein the C12 to C24 hydrocarbon comprises mineral oil.

6. The composition of Claim 1, wherein the mid-chain triglyceride comprises a compound of the formula $CH_2(OOCR_1)CH(OOCR_2)CH_2(OOCR)_3$, wherein R_1, R_2 , and R_3 are the same or different and are each independently a C6 to C12 branched or unbranched alkyl group.

7. The composition of Claim 1, wherein the C26 to C36 hydrocarbon comprises squalane.

8. The composition of Claim 1, wherein the cholesteryl ester comprises cholesteryl behenate.

9. The composition of Claim 1, wherein the ester of a C10 to C24 fatty acid and a C10 to C20 alcohol comprises steraryl palmitate or palmitic acid steraryl ester.

10. The composition of Claim 1, wherein the ester of a C10 to C24 fatty acid and a C21 to C34 alcohol comprises myricyl palmitate.

11. The composition of Claim 1, wherein the ester of a C10 to C24 fatty acid and a C21 to C34 alcohol comprises bleached or unbleached beeswax.

12. The composition of Claim 11. wherein the beeswax is chosen from natural beeswax and artificial beeswax.

13. The composition of Claim 1, wherein the polar lipid comprises a phospholipid.

14. The composition of Claim 13, wherein the phospholipid comprises L-α-phosphatidylcholine.

15. The composition of Claim 1, comprising:
    a) from about 35 percent to about 65 percent by weight of the C12 to C24 branched or unbranched hydrocarbon;
    b) from about 1 percent to about 15 percent by weight of the mid-chain triglyceride;
    c) from about 10 percent to about 25 percent by weight of the C26 to C36 branched or unbranched hydrocarbon;
    d) from about 5 percent to about 15 percent by weight of the cholesteryl ester;
    e) from about 2 percent to about 15 percent by weight of the ester of a C10 to C24 fatty acid and a C10 to C20 alcohol;
    f) from about 2 percent to about 15 percent by weight of the ester of a C10 to C24 fatty acid and a C21 to C34 alcohol;
    g) from about 0.5 percent to about 5 percent by weight of the glycerol; and
    h) from about 2 percent to about 10 percent by weight of the polar lipid.

16. A composition comprising:
    a) mineral oil or a mixture comprising C12 to C24 alkanes;
    b) a mid-chain triglyceride comprising a compound of the formula $CH_2(OOCR_1)CH(OOCR_2)CH_2(OOCR)_3$, wherein R_1, R_2 , and R_3 are the same or different and are each independently a C6 to C12 branched or unbranched alkyl group;
    c) squalane;
    d) cholesteryl behenate;

e) steraryl palmitate or palmitic acid steraryl ester;
f) natural or artificial beeswax;
g) glycerol; and
h) L-α-phosphatidylcholine.

17. The composition of Claim 16, comprising:
a) from about 35 percent to about 65 percent by weight of the mineral oil or the mixture comprising C12 to C24 alkanes;
b) from about 1 percent to about 15 percent by weight of the mid-chain triglyceride;
c) from about 10 percent to about 25 percent by weight of the squalane;
d) from about 5 percent to about 15 percent by weight of the cholesteryl behenate;
e) from about 2 percent to about 15 percent by weight of the steraryl palmitate or palmitic acid steraryl ester;
f) from about 2 percent to about 15 percent by weight of the ester of natural or artificial beeswax;
g) from about 0.5 percent to about 5 percent by weight of the glycerol; and
h) from about 2 percent to about 10 percent by weight of the L-α-phosphatidylcholine.

18. The composition of Claim 17, wherein the mineral oil or the mixture comprising C12 to C24 alkanes is from about 40 percent to about 60 percent by weight of the composition; and the mid-chain triglyceride is from about 1 percent to about 10 percent by weight of the composition.

19. A method of making a composition for treatment of a dry eye condition in an individual in need thereof, the method comprising the steps of:
a) contacting mineral oil or a mixture comprising C12 to C24 alkanes; a mid-chain triglyceride comprising a compound of the formula $CH_2(OOCR_1)CH(OOCR_2)CH_2(OOCR)_3$, wherein R_1, R_2 , and R_3 are the same or different and are each independently a C6 to C12 branched or unbranched alkyl group; a C26 to C36 branched or unbranched hydrocarbon; glycerol; and a polar lipid, to produce a first mixture of ingredients;

b) maintaining the first mixture at first conditions sufficient to disperse the ingredients and form a first solution or a first suspension;

c) contacting the first mixture with a cholesteryl ester; an ester of a C10 to C24 fatty acid and a C10 to C20 alcohol; an ester of a C10 to C24 fatty acid and a C21 to C34 alcohol to produce a second mixture; and

d) maintaining the second mixture at second conditions sufficient to disperse the ingredients of the first mixture with the second mixture and thereby form the composition.

20. The method of Claim 19, wherein the first and second conditions comprise a temperature from about 50 degrees Celsius to about 95 degrees Celsius.

21. The method of Claim 19, wherein the first conditions comprise agitating the first mixture for a first period of time sufficient to achieve homogeneity of appearance of the first mixture; and wherein the second conditions comprise agitating the second mixture for a second period of time sufficient to achieve homogeneity of appearance of the second mixture.

22. A method for treating a dry eye condition in an individual in need thereof, comprising administering a therapeutically effective amount of the composition of any one of Claims 1-18.

23. A method for treating a disorder chosen from lipid tear deficiency; aqueous tear deficiency; a combination of lipid tear deficiency and aqueous tear deficiency; epidermal dysplasia; Stevens Johnson Syndrome; meibomian gland diseases; rosacea; blepharitis; lagophthalmos; chemical injuries; thermal burn injuries; and diseases causing meibomian gland dysfunction, comprising administering to an individual in need thereof a therapeutically effective amount of the composition of any one of Claims 1-18.

24. A method for treating dry eyes in an individual in need thereof, comprising:

a) using kinetic analysis of tear interference images to analyze a precorneal lipid film spread of the individual;

b) determining whether or not the precorneal lipid film spread is characteristic of lipid tear deficiency; and

if the film spread is characteristic of lipid tear deficiency, administering a therapeutically effective amount of the composition of any one of Claims 1-18.

25. The method of any one of Claims 22, 23, and 24, wherein the composition is administered by a method comprising applying the composition to the outside skin of a lower eyelid or to the outside skin of an upper eyelid, and allowing the composition to diffuse onto the eye, thereby achieving sustained release of the composition and preventing or minimizing blurring of vision by the composition.

26. The method of Claim 25, wherein the composition is applied to the inferior lid margin of the lower eyelid or to the superior lid margin of the upper eyelid.

27. The method of Claim 22 additionally comprising administering simultaneously, separately, or sequentially; and topically to the skin, to the ocular surface, or orally, to the patient in need thereof a pharmaceutically active substance chosen from a steroid, an antibiotic, cyclosporin A, and an antioxidant.

28. The method of any one of Claims 22-26, wherein the amount of composition that is administered in an application is from about 10 micrograms to about 50 micrograms of composition applied to an eyelid.

29. The method of Claim 23, wherein the composition is applied to the outside skin of the lower eyelid and to the outside skin of the upper eyelid at least once a day for a period of time sufficient to obtain an improvement in the dry eye condition or a decrease in severity of a symptom of the dry eye condition.

30. The method of Claim 25, wherein the composition is applied to about one square centimeter of eyelid surface in each administration.

31. The method of any one of Claims 22-30, wherein the composition is applied from about 1 time per day to about 6 times per day.

32. The method of any one of Claims 22 -31, wherein the composition (52) is applied by urging the composition (52) out of at least one restricted discharge aperture (32) in a frontal edge (30) of an applicator (10) comprising:
a hollow housing (40) defining a cylindrical-shaped reservoir (50) containing the composition (52), the reservoir (50) in fluid communication with the aperture (32);
a plunger (82) for resiliently urging the composition (52) out of the reservoir (50) through the aperture (32), the plunger (82) adapted to fit within the reservoir (50) and to be moveable into the reservoir (50); and
an actuator means (70) for selectively moving the plunger (82) from a first position wherein the composition (52) is within the reservoir (50) to a second position wherein a portion of the composition (52) is urged through the aperture (32) and applied to the outside skin of the lower eyelid or to the outside skin of the upper eyelid.

33. The method of any one of Claims 22 -32, wherein a surface of the plunger (82) is in contact with a leading edge (81) of a cylindrical-shaped spindle (80) positioned within a housing (90) of the applicator (10), the spindle (80) having external spiral threads capable of frictionally engaging tabs (46) attached to the actuator (70); and
wherein the actuator (70) is rotatable and is frictionally fit over the hollow housing (40); the method further comprising rotating actuator (70) to cause tabs (46) to engage the external threads of spindle (80) and pull the plunger (82) in contact with the spindle (80) from the first position to the second position, thereby controllably urging a portion of composition (52) through the aperture (32) for application to the skin of the eyelid.

34. A method for treating a dry eye condition by administering an ointment comprising at least one lipid to an individual in need thereof, while achieving sustained release of the ointment and preventing a blurring of vision by the ointment, the method comprising administering a therapeutically effective amount of the ointment to the inferior lid margin of the outside skin of the lower eyelid or to the superior lid margin of the outside skin of the upper eyelid, and allowing the ointment to diffuse onto the eye.

35. The method of Claim 34, wherein the ointment is substantially free of water and substantially free of an artificial surfactant.

36. The use of a composition according to any one of Claims 1-18 in the manufacture of a medicament for the treatment of a condition chosen from lipid tear deficiency, aqueous tear deficiency, a combination of lipid tear deficiency and aqueous tear deficiency, epidermal dysplasia, Stevens Johnson Syndrome, meibomian gland diseases, rosacea, blepharitis, lagophthalmos, chemical injuries, thermal burn injuries, and diseases causing meibomian gland dysfunction.

37. The use of a composition comprising a polar lipid and a non-polar lipid, wherein the composition is substantially free of water; substantially free of an artificial surfactant; and substantially free of an artificial polymer, in the manufacture of a medicament for the treatment of a condition chosen from lipid tear deficiency, aqueous tear deficiency, a combination of lipid tear deficiency and aqueous tear deficiency, epidermal dysplasia, Stevens Johnson Syndrome, meibomian gland diseases, rosacea, blepharitis, lagophthalmos, chemical injuries, thermal burn injuries, and diseases causing meibomian gland dysfunction.

38. The use of Claim 37, wherein delivery of the composition comprises administering a therapeutically effective amount of the composition to the inferior lid margin of the outside skin of the lower eyelid or to the superior lid margin of the outside skin of the upper eyelid, and allowing the composition to diffuse onto the eye, thereby achieving sustained release of the composition and preventing a blurring of vision by the composition.